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## 510(k) Summary

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92

### Submitter's Information

| | |
|---|---|
| *Company name* | *Materialise* N.V. |
| *Establishment registration number* | 3003998208 |
| *Street Address* | Technologielaan 15 |
| *City* | Leuven |
| *Postal code* | 3001 |
| *Country* | Belgium |
| *Phone number* | +32 16 39 62 80 |
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| *Principal Contact person* | Alexandra Razzhivina |
| *Contact title* | Regulatory Officer |
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| *Additional contact person* | Karl vom Berge |
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| *Additional contact person* | Wim Claassen |
| *Contact title* | Project Manager |
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### Submission date

The date of the Traditional 510(k) submission is December 23rd, 2011.

### Submission information

| | |
|---|---|
| *Trade Name* | Zimmer Patient Specific Instruments<br>Zimmer Patient Specific Instruments Planner |
| *Common Name* | Knee prosthesis |
| *Classification Name* | Knee joint patellofemorotibial polymer /metal /polymer semi-constrained cemented prosthesis<br>Knee joint patellofemorotibial metal / polymer porous-coated uncemented prosthesis |
| *Product code* | JWH (21 CFR 888.3560)<br>MBH (21 CFR 888.3565)<br>OOG (21 CFR 888.3560) |

### Predicate Devices

The predicate device to which substantial equivalence is claimed to:

| | |
|---|---|
| *Trade or proprietary or model name* | Zimmer Patient Specific Instrument System 2.5 |
| *510(k) number* | K111492 |
| *Decision date* | 17/02/2010 |
| *Product code* | JWH (21 CFR 888.3560)<br>MBH (21 CFR 888.3565) |
| *Manufacturer* | Materialise N.V. |

| | |
|---|---|
| *Trade or proprietary or model name* | SignatureTM Personalized Patient Care System |
| *510(k) number* | K102795 |
| *Decision date* | 02/02/2011 |
| *Product code* | JWH (21 CFR 888.3560)<br>OIY (21 CFR 888.3560)<br>MBH (21 CFR 888.3565)<br>OOG (21 CFR 888.3565) |
| *Manufacturer* | Materialise N.V. |

### Device Description

The subject device Zimmer Patient Specific Instruments System 4.0 is an upgrade of the predicate device Zimmer Patient Specific Instruments System 2.5 and is designed to assist a surgeon in the placement of total knee replacement components for Zimmer NexGen CR-FLEX fixed bearing, Zimmer NexGen CR fixed bearing, Zimmer NexGen LPS-FLEX fixed bearing, Zimmer NexGen LPS fixed bearing and Zimmer Gender Solutions Natural – Knee Flex fixed bearing prostheses. The system consists of a software device, branded as Zimmer Patient Specific Instruments Planner (ZPSIP) and a hardware component, branded as Zimmer Patient Specific Instruments (ZPSI). Use of Zimmer Patient Specific Instruments is limited to the treatment of intra-articular deformities only.

### Intended Use

The **Zimmer Patient Specific Instruments System** is intended to be used as a surgical instrument to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Zimmer Patient Specific Instruments System is to be used with Zimmer NexGen CR-Flex fixed bearing, Zimmer NexGen CR fixed bearing, Zimmer NexGen LPS-Flex fixed bearing, Zimmer NexGen LPS fixed bearing and Zimmer Gender Solutions Natural – Knee Flex fixed bearing prostheses families only.

The Zimmer Patient Specific Instruments are intended for single use only.

### Functioning of the Device

The Zimmer Patient Specific Instruments System 4.0 generates a pre-surgical plan based on computed tomography (CT) image data sets using the Zimmer Patient Specific Instruments Planner. The software device then is used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Next, Zimmer Patient Specific Instruments are designed and manufactured based on the approved pre-surgical plan. Zimmer Patient Specific Instruments are patient specific templates which transfer the pre-operatively determined positioning of the chosen total knee replacement components to the patient intra-operatively, assisting the surgeon in positioning and aligning the actual total knee replacement components by guiding and marking drill locations.

### Technological Characteristics

A detailed comparison shows the subject device is substantially equivalent in intended use, materials and performance characteristics to the proposed predicate devices.

## Performance Data

Non-clinical tests have been performed to assess the safety and effectiveness of the subject device. Testing verified that the accuracy and performance of the system is adequate to perform as intended.

## Summary

The characteristics that determine the functionality and performance of the subject device, the Zimmer Patient Specific Instruments System 4.0, are substantially equivalent to those cleared under K111492 and K102795. The Zimmer Patient Specific Instrument System will be manufactured in compliance with FDA and ISO quality system requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Materialise N.V.
% Ms. Alexandra Razzhivina
Technologielaan 15
Leuven, Belgium 3001

APR - 2 2012

Re: K113829
Trade/Device Name: Zimmer Patient Specific Instrument System 4.0
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: Class II
Product Code: JWH, MBH, OOG
Dated: March 21, 2012
Received: March 23, 2012

Dear Ms. Razzhivina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

**510(k) Number (if known):**

**Device Name:** **Zimmer Patient Specific Instruments System 4.0** (Zimmer Patient Specific Instruments Planner, Zimmer Patient Specific Instruments)

**Indications for Use:**

The **Zimmer Patient Specific Instruments System** is intended to be used as a surgical instrument to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The **Zimmer Patient Specific Instruments System** is to be used with Zimmer NexGen CR-FLEX fixed bearing, Zimmer NexGen CR fixed bearing, Zimmer NexGen LPS-FLEX fixed bearing, Zimmer NexGen LPS fixed bearing and Zimmer Gender Solutions Natural – Knee Flex fixed bearing prostheses families only.

The Zimmer Patient Specific Instruments are intended for single use only.

Prescription Use _ X ____ AND/OR Over-The-Counter Use __ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices



510(k) Number K113829